

U.S.S.N. 10/083,413

Filed: February 27, 2002

**AMENDMENT AND RESPONSE TO OFFICE ACTION****Remarks**

Claim 1 has been amended to incorporate the limitation of original claim 5 and to define agents which are provided in the bioadhesive carrier, as discussed below. Claim 1 has also been amended to recite specific herbal agents (herbs, herbal extracts, tinctures, and essential oils, see dependent claims) and specific classes of agents (defined at page 11, lines 14-18 and page 38, example 9) present in a *homeopathic* amount, which is an amount less than a therapeutically effective amount (page 35, example 8). Claims 2-6, 7-12, 14, 15, 19, and 22-26 have been amended to correct grammatical errors.

**Rejection Under 35 U.S.C. § 112, first paragraph**

Claims 1-4, 6-12 and 14-26 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled because one of ordinary skill in the art would have to engage in undue experimentation to determine if the amount of a homeopathic agent was a therapeutically effective amount. This rejection is respectfully traversed.

The claims have been amended to delete the term "therapeutically effective" and merely refers to "bioactive". The specific classes of compounds has also been significantly narrowed to defined sets of compounds. One skilled in the art would have no difficulty in obtaining or using these compounds.

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**AMENDMENT AND RESPONSE TO OFFICE ACTION****Rejection Under 35 U.S.C. § 112, second paragraph**

Claims 1-4, 6-12 and 14-26 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite with respect to the term "homeopathic agent". This rejection is respectfully traversed.

The term "homeopathic agent" is well understood by those skilled in the art, is defined in example 8 in the specification, and has been further defined by reference to specific compounds. Indeed, as demonstrated by the enclosed page from Stedman's Medical Dictionary, the term is routinely used. The most well known example of a homeopathic medicine are allergy shots, where the antigen is diluted to too low of a concentration to induce a reaction, then administered over a period of months or years to induce tolerance. Also enclosed is information from the National Institutes of Health website, which not only makes it clear that homeopathy is well known and accepted, but has been regulated by the FDA since 1938 in the same way as other over the counter medicines.

To facilitate prosecution, the claims have been limited to specific agents having known functions. The term "therapeutically effective" has been deleted to facilitate prosecution.

Herbal extracts, herbs, essential oils, and tinctures have been in medical use for thousands of years. It is well accepted that they have biological activity. Indeed, numerous researchers have utilized the knowledge that certain herbs and derivatives thereof have biological activity in order to extract the specific compounds contained therein which have the activity. Some well known examples include aspirin (willow bark) and taxol (pacific yew), to name just two of the

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most famous. Many compounds are acknowledged by the FDA as having biological activity.

The other claimed compounds are also well known: antiinflammatories, antihistamines, antimicrobial drugs, vitamins, antiulcer drugs, etc. These compounds as well as therapeutically effective dosages are known and therefore provide a definite reference point for the claimed compositions which require the use of an amount that is less than the therapeutically effective amount.

Allowance of claims 1-4, 6-12 and 14-17, 19, 22-26, and 38, as amended, is respectfully solicited.

Respectfully submitted,



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